DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

g1764d

August 2, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
SJN-01-15

Jorge Machado Ruiz
President and Owner
Necco, Inc. (dba Freshmart)
P.O. Box 744/Pueblo Station
Carolina,Puerto Rico 00986

Dear Mr. Machado:

On May 25, 2001, the Food and Drug Administration (FDA) conducted a Class I recall audit check inspection of your health food store located at Road 887, Km. 0.4, Carolina, P.R. 00986. The reported findings, obtained during the recall audit check, appear to violate Sections 301(c) and 402 (a) (1) of the Food Drug and Cosmetic Act (the Act).

Your firm has continued to sell a recalled nutritional supplement, "Nature's Plus Ultra-Zyme, Hypo-Allergenic 90 tablets" (product no. 4452, lots 1005942 and 1007110), after having been notified that this product was potentially contaminated with *Salmonella* microorganisms. The recalled tablets are adulterated per section 402(a)(1) of the Act because they contain a poisonous or deleterious substance, *Salmonella* microorganisms, which may render them injurious to health. It is a prohibited act (Section 301(c) of the Act) to receive an adulterated food in interstate commerce and deliver it or proffer delivery of it for sale.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility . You are responsible, with all other persons in positions of authority at your company, to assure that your firm operates in full compliance with the requirements of the Act. You should know that this violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing adulterated foods and obtaining a court injunction against you.

In addition, your firm failed to immediately follow-up the recall instructions for a product that could pose a serious health risk to consumers. Your firm did not attempt to contact consumers who had purchased the product, or if customers were not known, to post the recall notice in your store, as instructed in the recall letter.

You should notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, state the reason for delay and the time within which corrections will be completed.

We have notified the Secretary of Health for the Commonwealth of Puerto Rico of the findings of the recall audit check and have recommended that the Department of Health evaluate these findings and take any further action they deem necessary. Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernández Juncos Avenue, San Juan, Puerto Rico 0090-3223, Attention: Ms. Wanda J. Torres, Acting Compliance Officer.

Sincerely,

Wayne Matthews

Wayne Matthews
Acting District Director

Cc: Dr. Johnny Rullán
Secretary
Department of Health
Commonwealth of Puerto Rico
P.O. Box 70184
San Juan, PR 00936-8184